REMARKS

Rejection of Claims 8-54 - 35 U.S.C. §103(a)

In the Office Action, Claims 8-54 were rejected under 35 U.S.C. §103(a) as obvious over Fletcher-Haynes et al. U.S. Published Application No. US 2001/0034614 A1 (hereinafter "Fletcher-Haynes") in view of Otworth et al. U.S. Published Application No. US 2002/0059030 (hereinafter "Otworth").

Fletcher-Haynes does not fairly teach or suggest the invention claimed in Claims 8-54 for the following reasons.

Fletcher-Haynes is generally concerned with manipulating and optimizing blood collection procedures to maximize the type or amount of blood components that may be collected from a particular donor. As explained in paragraph 0162, these blood product components include platelets, plasma and RBCs. In certain paragraphs of Fletcher-Haynes, a disposable tubing set may be identified and recorded (Paragraph 0083), information may be supplied concerning the tubing set or bag used (including identifiers) for a particular blood component collection procedure (Paragraph 0125), or a final report may identify the tubing set that was used in a particular procedure

(Paragraph 0166).

However, unlike the present invention, Fletcher-Haynes does not fairly disclose or teach a system database with an inventory of blood component collection soft goods (Claim 8), such as a blood component collection kit, a blood component collection solution, and a blood component collection transfer pack (Claim 10). Nor does Fletcher-Haynes teach a system computer with a quarantine field for indicating that at least a portion of the blood component collection soft goods is quarantined (Claim 8). Of course, blood component collection soft goods may need to be quarantined for any of a variety of reasons including that the soft goods have previously been opened and are therefore not sterile, that the soft goods are damaged, that the soft goods are past an end of use date, that the soft goods have been superceded by a newer part number, or the like. See, generally, Paragraphs 0132, 0134-0135, 0261, 0268-0269, 0392-0393 and FIGS. 72-75 of the present patent application. In short, Fletcher-Haynes is not concerned with quarantining of unsuitable soft goods.

The rejections of specific claims will now be considered in further detail:

Claim 8: In the Office Action, it was noted that "soft goods" is being interpreted as including blood

products. To resolve this interpretation issue, Claims 8, 31 and 43 have been amended above to state that the blood component is collected in a blood component soft good. Thus, the soft good is the container or kit which holds the collected blood component.

As mentioned above, Fletcher-Haynes is not concerned with a system database with an inventory of blood component collection soft goods, nor with a system computer with a quarantine field for indicating that at least a portion of the blood component collection soft goods is quarantined.

For example the inventory disclosed in Paragraph 0195 of Fletcher-Haynes is of the blood components (also referred to as "units"), i.e., platelets, plasma and RBCs, that have previously been collected. Such units may be transferred between hospitals or collection centers. Similarly, Paragraph 0162 is concerned with the current collection status of inventory of such blood components, and has nothing to do with the quarantining of soft goods including an interface with a quarantine field for indicating the quarantine status, as claimed in Claim 8.

It is suggested in the Office Action that Otworth discloses a quarantine field or the quarantining of blood component soft goods in FIG. 16 and Paragraph 0222. However, that is objected to for the reasons expressed

below. See, the discussion of Otworth below.

Claim 9: The cited Paragraphs 0022, 0083, 0125 and 0162 of Fletcher-Haynes have nothing to do with an identification of quarantined soft goods, as explained above. Otworth does not cure this deficiency, as explained below.

Claims 23, 25-28, 39-42, 44 and 51-54: As presented above, Fletcher-Haynes does not fairly teach or disclose providing separate inventory data for each of the plurality of different types of soft goods, modifying such inventory data, generating a notification when the inventory is below a predetermined value, providing a reorder option for the soft goods, transmitting the reorder option to a remote access service for restocking, or communicating an identification of the quarantined soft goods to the system database. Otworth does not cure these deficiencies, as explained below.

Claim 31: As explained above with respect to Claim 8, Fletcher-Haynes is does not fairly teach or suggest a system database with an inventory of blood component collection soft goods nor does Fletcher-Haynes fairly teach or suggest indicating that a portion of the soft goods inventory is quarantined. Thus, Fletcher-Haynes similarly does not teach a computer readable medium with a code

segment that provides for accessing a system database with an inventory of blood component collection soft goods and a code segment that indicates that a portion of the soft goods inventory is quarantined, as claimed in Claim 31. Moreover, the combination of Otworth with Fletcher-Haynes in the rejection of Claim 31 is objected to for the reasons expressed below.

As also noted above with respect to Claim 8, Claim 31 has been amended to state that the blood component is collected in a blood component soft good. Thus, the soft good is the container or kit which holds the collected blood component.

Claim 43: As explained above with respect to Claim 8, Fletcher-Haynes is does not fairly teach or suggest a system database with an inventory of blood component collection soft goods nor indicating that a portion of the soft goods inventory is quarantined. Thus, Fletcher-Haynes similarly does not teach any methods for accessing a system database having an inventory of blood component collection soft goods and for indicating that a portion of the soft goods inventory is quarantined, as claimed in Claim 43. Moreover, the combination of Otworth with Fletcher-Haynes in the rejection of Claim 43 is objected to for the reasons expressed below.

As also noted above with respect to Claim 8, Claim 43 has also been amended to state that the blood component is collected in a blood component soft good. Thus, the soft good is the container or kit which holds the collected blood component.

The Otworth reference is inconsistent with the present invention as claimed in Claims 8-54. Otworth is concerned with a system and methods of performing testing with a testing kit 100. In the example of FIG. 16, which is cited in the Office Action, the subject may be quarantined. FIG. 16 is discussed in Paragraphs 0212-0217. In particular, the last portion of Paragraph 0212 states:

> "Examples of such a quarantine may include a quarantine of a human or animal subject due to a suspected or actual disease, or a quarantine of an immigrating subject based on immigration laws, regulations or requirements. Further still, an exemplary quarantine may involve isolating a source of drinking water or isolating a body of water from human contact to prevent the spread of disease or other contaminants in the water."

Clearly, Otworth is concerned with quarantining a human being, an animal, a body of water or the like; not his test kit. More specifically, Otworth does not relate

to any blood component collection procedures (Claims 8-54). There is no appreciation in Otworth for preventing the use of quarantined blood component collection soft goods (Claims 8 and 43), for keeping an inventory of quarantined blood component soft goods (Claims 11, 25, 39, 43 and 51), for separately identifying a plurality of different types of quarantined blood component soft goods (Claims 10, 23, 24 and 44), for reordering quarantined blood component soft goods based in part on the present inventory of quarantined soft goods (Claims 27, 41 and 53), for providing a notification when the inventory of blood component soft goods is below a predetermined value (Claim 26, 40 and 52), or for providing a quarantine field for indicating that at least a portion of the blood component soft goods are quarantined (Claim 8).

Thus, there is no reason that one skilled in the art would be led to combine Fletcher-Haynes with Otworth. To do so would mean that the donors and the collected blood products of Fletcher-Haynes, not the blood component soft goods, would be subjected to testing for disease or contamination, and that the donors or collected blood products could potentially be subjected to quarantine. However, as noted above, that is not what is claimed in the present invention. Thus, the combination of Fletcher-

Haynes and Otworth teach away from the present invention and make it non-obvious.

The Applicants are not in agreement with the reasons cited in many of the remaining rejections of other dependent claims that are not specifically addressed above. However, since independent Claims 8, 31 and 43 are believed to be patentable over the cited art, the remaining dependent claims should also be allowable as placing additional limitations on these independent claims.

It is also noted that while Claim 54 was rejected in the Office Action, no specific grounds of rejection of this claim are set forth. Clarification is requested.

Reconsideration and removal of the rejections of Claims 8-54 are respectfully solicited.

CONCLUSION

For the foregoing reasons, it is believed that Claims 8-54 patentably distinguish over the prior art and that these claims are in condition for allowance. Early allowance is respectfully solicited.

A petition for a one-month extension of time to make the filing of this amendment timely is attached.

It is believed that no fees are due. However, if any fees are applicable, kindly charge any such fees to our deposit account number 50-1039.

The Examiner is invited to call the undersigned to further discuss any of these matters.

Respectfully submitted,

June 30, 2006
Dated

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